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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/867,753	05/31/2001	Bertram Weiss	SCH-1810	5703

23599 7590 09/26/2003

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EXAMINER

MONDESI, ROBERT B

ART UNIT PAPER NUMBER

1653

DATE MAILED: 09/26/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/867,753	WEISS ET AL.	
	Examiner	Art Unit	
	Robert B Mondesi	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 22 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) 2-13 and 15-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on May 31, 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention I, **Claim 1 and 14**, filed August 26, 2003, is acknowledged. The traversal is on the ground(s) that all of the inventions are related in concept and theory and therefore the examination of all inventions would not pose an undue burden on the Examiner. This is not found persuasive because the search of the inventions is not coextensive, that is, the search of computers would not have resulted in a search of the elected nucleic acid, for example. In addition a search for the nucleic acids would not have resulted in a search of or for computers.

The requirement is still deemed proper and is therefore made FINAL.

Claims 2-13 and 15-17 are withdrawn from further consideration by the Examiner as directed to non-elected inventions.

Priority

The current application filed on May 31, 2001 claims priority to foreign application, Germany 10027170.7, filed on May 31, 2000. A certified translation of the German language document 10027170.7 has not been provided.

Information Disclosure Statement

An IDS has not been filed with this application.

Specification

The disclosure is objected to because of the following informalities: PEM needs to be spelled out in the first instance of use.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In **claim 1** the term "corresponds" allows for a multiplicity of interpretations. For example, corresponds in this case, could mean; a nucleotide sequence that has a high degree of homology to the original, a nucleotide sequence that comprises the original, or a nucleotide sequence that resembles the original in regards to structural integrity.

In **claim 1** the statement "a nucleotide sequence that corresponds to the sequence from (a), [Seq ID No. 1], against the back drop of the degeneration of the genetic code" is indefinite in this case, because by definition a degenerative code consists of many different sequences. It is not clear which sequence in particular is being referred to. In order to identify these sequences each would have to have a Seq ID No. Also in **claim 1** the phrase " a nucleotide sequence that hybridizes under stringent conditions with sequences from (a) or (b) " is indefinite, because (b) encompasses numerous sequences that are not identified with appropriate Seq ID Nos.

In claim 1 the phrase "hybridizes under stringent conditions with sequences" is indefinite. The applicant has asserted the defined stringent

conditions in the specification with a set of broad conditions. A consequence of such broad conditions is often nonspecific binding between two DNA sequences. It is unclear what the applicants invention is without defining further the phrase, "hybridizes under stringent conditions with sequences". Stringent conditions, in this case, need to be further defined by providing specific washing conditions as opposed to a range of conditions.

In **claim 14** PEM needs to be spelled out in first instance of usage. The statement fragment thereof is indefinite because the size and content of the fragment needs to be specified with a Seq ID No. The nucleic acid that codes for "human PEM" needs to be indicated with a Seq ID No.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "transfixed" in **claim 14** is used by the claim to mean "transformed or transfected", while the accepted meaning (see Webster's II dictionary 1984, page 794) is "awe, mesmerized, hypnotized." The term is indefinite because the specification does not clearly redefine the term.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The DNA as claimed , encodes a polypeptide having an amino acid sequence duplicative that of the human genome Reid et al (entire document) or a cellular precursor thereof and possesses the biological and functional properties of a naturally occurring polypeptide, PEM and therefore does not constitute patentable subject matter absent isolated and purified.

Claim Rejections - 35 USC § 102

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(e) as being anticipated by Rosen et al. US application 09/764864. Rosen et al, teach a polynucleotide with nucleic acid sequence (claim 1, Seq ID No. 368) that is 100% match of the nucleic acid sequence (Seq ID No. 1) in **claim 1**. Thus Rosen et al. teach all the elements of **claim 1** and this claim is anticipated under 35 USC 102(e).

Claim 14 is rejected under 35 U.S.C. 102(b) as being anticipated by Reid et al.. Reid et al. (page 33589, column 1-2) in the section titled materials and methods, teach the preparation of cells containing a nucleic acid that codes for human PEM (present **claim 14**). Thus Reid et al. teach all the elements of **claim 14** and this claim is anticipated under 35 USC 102(b).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert B Mondesi whose telephone number is 703-305-4445. The examiner can normally be reached on 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on 703-308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.


Robert Mondesi
Patent Examiner
09-22-03


CHRISTOPHER S. F. LOW
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